

**§ 886.1630 AC-powered photostimulator.**

(a) *Identification.* An AC-powered photostimulator is an AC-powered device intended to provide light stimulus which allows measurement of retinal or visual function by perceptual or electrical methods (e.g., stroboscope).

(b) *Classification.* Class II.

**§ 886.1640 Ophthalmic preamplifier.**

(a) *Identification.* An ophthalmic preamplifier is an AC-powered or battery-powered device intended to amplify electrical signals from the eye in electroretinography (recording retinal action currents from the surface of the eyeball after stimulation by light), electrooculography (testing for retinal dysfunction by comparing the standing potential in the front and the back of the eyeball), and electromyography (recording electrical currents generated in active muscle).

(b) *Classification.* Class II.

**§ 886.1650 Ophthalmic bar prism.**

(a) *Identification.* An ophthalmic bar prism is a device that is a bar composed of fused prisms of gradually increasing strengths intended to measure latent and manifest strabismus (eye muscle deviation) or the power of fusion of a patient's eyes.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in part 807, subpart E of this chapter. The device also is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[52 FR 33355, Sept. 2, 1987, as amended at 53 FR 35605, Sept. 14, 1988]

**§ 886.1655 Ophthalmic Fresnel prism.**

(a) *Identification.* An ophthalmic Fresnel prism is a device that is a thin plastic sheet with embossed rulings which provides the optical effect of a prism. The device is intended to be applied to spectacle lenses to give a prismatic effect.

(b) *Classification.* Class I. The device is exempt from the premarket notification

procedures in part 807, subpart E of this chapter. The device also is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[52 FR 33355, Sept. 2, 1987, as amended at 53 FR 35605, Sept. 14, 1988]

**§ 886.1660 Gonioscopic prism.**

(a) *Identification.* A gonioscopic prism is a device that is a prism intended to be placed on the eye to study the anterior chamber. The device may have angled mirrors to facilitate visualization of anatomical features.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[52 FR 33355, Sept. 2, 1987, as amended at 53 FR 35605, Sept. 14, 1988; 59 FR 63013, Dec. 7, 1994]

**§ 886.1665 Ophthalmic rotary prism.**

(a) *Identification.* An ophthalmic rotary prism is a device with various prismatic powers intended to be handheld and used to measure ocular deviation in patients with latent or manifest strabismus (eye muscle deviation).

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in part 807, subpart E of this chapter. The device also is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[52 FR 33355, Sept. 2, 1987, as amended at 53 FR 35605, Sept. 14, 1988]

**§ 886.1670 Ophthalmic isotope uptake probe.**

(a) *Identification.* An ophthalmic isotope uptake probe is an AC-powered device intended to measure, by a probe which is placed in close proximity to the eye, the uptake of a radioisotope (phosphorus 32) by tumors to detect